

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Martin J. PAGE et al. Conf.: Unassigned
Appl. No.: NEW Group: Unassigned
Filed: January 28, 2004 Examiner: UNASSIGNED
For: A GLYCOSYLATED ANTIBODY (as amended)

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION WITH CONTINUATION-IN-PART OR
RULE 1.53(b) CONTINUATION OR DIVISIONAL APPLICATION)

Assistant Commissioner for Patents
Washington, DC 20231

January 28, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicants hereby submit an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449 forms, attached hereto.

II. COPIES (check at least one box)

- a. ☐ Submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☒ The only document listed on the PTO-1449 that is enclosed is the Ebert, 1991, Dissertation, University for Soil Cultivation in Vienna, Austria. This reference was newly identified by the Applicants and not previously submitted in the parent application.

c. ☒ **References Previously Cited or Submitted**

Pursuant to 37 C.F.R. § 1.98(d), consideration of information listed on the PTO-1449 forms is requested since any patents, publications, or other information which are listed on the PTO-1449 forms but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

<u>U.S. Appl. Nos.</u>	<u>U.S. Filing Dates</u>
10/145,712	May 16, 2002
09/642,826	August 22, 2000
08/475,607	June 7, 1995
08/155,864	November 23, 1993
08/046,893	April 15, 1993
07/943,143	September 10, 1992
07/777,730	October 16, 1991

III. CONCISE EXPLANATION OF THE RELEVANCE
(check at least one box)

a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The attached patents, publications, or other information in the English language do not require a statement of relevancy.

b. ☐ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

c. ☒ **OTHER**

The following additional information is provided for the Examiner's consideration.

The undersigned wishes to bring to the Examiner's attention various information that may be relevant to the examination of the above-identified application. It is hoped that this summary of various information will allow the Examiner to conduct a more

meaningful review of the information. Copies of references and Exhibits, to which the Examiner may want to refer, are enclosed with the IDS and are listed on PTO-1449. If the Examiner determines that he would like to review copies of certain Exhibits that are not included with this IDS, he is requested to contact the undersigned and copies will be provided to the Examiner as soon as possible. As the Examiner has been advised, U.S. Patents 5,545,403; 5,545,404 and 5,545,405 of Page are involved in Interference Number 104,532. The '403 and '405 patents are also involved in litigation. A jury verdict in favor of Genentech verdict has been rendered and GlaxoSmithKline is appealing the jury verdict.

Prior Art References and Activities

Various activities occurred prior to the October 16, 1991 U.S. filing date of the present application that the Examiner may determine is relevant to patentability.

UAB Clinical Trials/B72.3 antibodies

In the time period between 1989 and 1991, clinical trials were conducted at the University of Alabama (UAB) by Dr. LoBuglio and others. These clinical trials used a chimeric antibody (B72.3) conjugated to a radionuclide ¹³¹I that specifically bound to the antigen TAG-72 (tumor associated glycoprotein 72). Testimony was presented that the B72.3 antibody may have been expressed in and glycosylated by CHO cells. (LoBuglio Deposition, page 48 line 17 to page 49, line 17 and page 240, line 10 to page 241, line 14.) Additional testimony regarding the B72.3 was presented at the trial in the related district court litigation (Trial Transcript 2770:15-2775:9, 2778:23-2785:1, 2815:16-2819:6, 2821:8-2822:22)

The following references pertain to mAb B72.3 and the trials at University of Alabama:

- Baker, et al 1991 Antibody, Immunoconjugates, and Radiopharmaceuticals, Vol. 4, No. 4 (1991)
Bodmer, et al 1993 U. S. Patent 5,219,996
Colcher et al. 1989 Cancer Res. 49:1738-1745
Harris et al. 1990 Proc. 34th Oholo Conf, Eilat, Israel pgs. 465-477
Khazaeli et al. 1991 Cancer Res. 51:5461-5466
Khazaeli et al. 1990 HER010300098/315 Abst. Sub. 37th Ann. Mtg of Soc of Nucl. Med.
Khazaeli et al. 1990 HER010300100/317 Abst. Sub. 3rd Conf. On Radioimmunodetect...
Khazaeli et al. 1991 Can. Res. 51:5461-5466
HER010300319 Abst. Sub. 6th Intl. Conf. On Monoclonal Anti.
Khazaeli et al. 1991 Immunoconj.

Khazaeli et al. 1992 J. of Clin. Immunol. 12(2):116-121
HER010300488-517 "Frequent Anti-V Region Immune Resp. to Mouse..."

Khazaeli et al.
LoBuglio & Saleh 1992 Am. J. Med. Sci. 304(3):214

LoBuglio et al. 2000 Deposition Transcript from litigation/interference.

LoBuglio et al. 1989 PNAS USA 86:4220-4224

LoBuglio et al. 1990 HER010300318 Abst. Sub. 3rd Conf. On Radioimmunodetect...
Adv. In Appl. Of Monoclonal Anti. In Clin. Oncol. Chap. 33 pp. 291-295

LoBuglio et al. 1991 291-295

LoBuglio et al. 1992 HER010300518 Abst. Sub. ASCO Ann. Mtg, Houston, TX.

Meredith 1990 Protocol: UAC 180 NCI:T89-0144 (NCI/CTEP Sheets)

Meredith et al. 1989 Protocol: UAC 180

Meredith et al. 1990 Protocol: UAC 180 (Amended?)

Meredith et al. 1989 Protocol: UAC 079

Meredith et al. 1990 HER010300313 Abst. Sub. 37th Ann. Mtg. For Soc. Of Nuc. Med.

Meredith et al. 1991 HER010300321 Abst. Sub. ASCO Ann. Mtg, Houston, TX.

Meredith et al. 1991 HER010300322 Abst. Sub. 8th Intl. Hammersmith Mtg, Greece

Meredith et al. 1991 HER010300323 Abst. Sub. 38th Ann. Mtg. Soc. Of Nuc. Med.

Meredith et al. 1991 J. Nuc. Med. 32(6):1162-1168

Meredith et al. 1992 Antibod. Immunoconj. & Radiopharm. 5(1):75-80

Meredith et al. 1992 J. Nuc. Med. 33(1):23-29

Meredith et al. 1992 J. Nuc. Med. 9(33):1648-1653

Meredith et al. 1992 J. Nucl. Med. 33:29

Meredith et al. 1995 J. Nuc. Med. 36:2229-2233

HER010300320 Abst. Sub. "Comp. localization of murine and chimeric B72.3..."

Meredith et al. HER010300324 Abst. Sub. 7th Intl. Conf. On Monoclo. Anti. Immunocoj.

Meredith et al. HER010300434-448 "Effect of Human Immune Resp. on Repeat Courses..."

Meredith et al. HER010300519-544 "Dose Fraction of Radiolabeled Antibodies in Patients..."

Meredith et al. Med. Physics "Dosimetry of Solid Tumors"

Meredith et al. 1993

Meredith et al. 1989 Amended Protocol: UAC 180
HER010300097/314 Abst. Sub. 5th Cong. - WFNMB&B, Montreal, Canada

Meredith et al. 1990 HER010300099/316 Abst. Sub. 3rd Conf. On Radioimmunodetect...

Primus et al. 1990 Cancer Immunol. & Immunother. 31:349

Whittle et al. 1987 Protein Eng. 1(6):499-505

Yarrenton 2000 Deposition in Interference 104,532

1990 Status Report w/ Master Order Agreement

1990 Status Report: Phase I Contract - Cancer Therapy

1991 Status Report Phase I Contract (N01-CM-97611)

1992 Status Report Phase I Contract (N01-CM-97611)

1994 Status Report: Phase I Contract - Cancer Therapy
Phase 1 Contract - CTEP Program (N01-CM-97611)

1990 On Study Registration

It is submitted that the claims of the present application distinguish from the University of Alabama Clinical Trials.

Anti-CD20 antibodies

A number of patents have issued to Robinson et al, including U.S. Patents. 5,500,362, 5,721,108 and 6,120,767. A related PCT publication is WO 87/02671. Applicants will refer to the oldest patent, U.S. Patent 5,500,362, for purposes of discussion. According to the examples of the '362 patent, the recombinant antibody was expressed in Sp2/0 cells (see Col. 18, lines 5-11).

Thus, it would seem that Sp2/0 cells would be the preferred cell line. Other expression hosts are also mentioned, including yeast. See Col. 9, lines 53-64 where yeast is indicated as being "one preferred host" (Col. 9, line 53) along with bacterial hosts, such as *E. coli*, *Salmonella typhimurium*, *Serratia marcescens* and various *Pseudomonas* species (Col. 11, lines 1-8) and mammalian cells PcX63Ag8, Vero cells or CHOK1 (Col. 11, lines 58-63). The '362 patent contains no description of the actual preparation or characterization of an antibody expressed in CHO cells. Since this patent does not teach the actual preparation of antibodies in CHO cells, and since it does teach the actual production of antibodies in Sp2/0 cells, one skilled in the art would conclude that Sp2/0 cells would be the cell line of choice.

The following references pertain to anti CD-20 antibodies:

Robinson et al.	1996	
		USP 5500362
Robinson et al.	1998	USP 5721108
Robinson et al.	2000	USP 6120767
Trial Transcript,		
2763:17-2767:16,		
2792:21-24,		
2793:10-14		

Anti-CEA Antibodies

Various prior art references teach the preparation of chimeric anti-CEA antibodies. These references will be divided into two groups, the "Shively references" and the "Cabilly references".

Shively References

Various anti-CEA recombinant antibodies are reported in various references in which Shively is either an author or a co-author. Some of these references describe expression of the antibodies in either Sp2/0 cells or CHO cells. However, the data

for antibodies expressed in Sp2/0 cells is more complete and therefore one must assume that Sp2/0 cells are more preferred. In addition, Dr. Shively testified in a Declaration that he contemplated conjugating these antibodies to a radionuclide before using the antibody for therapy (Declaration of Shively of October 30, 2000) and testified in a deposition that he did not contemplate using his antibodies for immunotherapy, but only radioimmunotherapy because "CEA is a poor target antigen for effector function." (See, Shively Deposition Transcript of January 12, 2001 page 56, lines 18-20). These references are discussed in some detail in Cabilly Preliminary Motion 1 and the related Opposition and Reply.

Cabilly References

The Cabilly references include US Patent 4,8176,567, EP 0125023 A1, EP 0125023 B1 and Cabilly et al, PNAS USA 81(11):3273-3277. These references report actual expression of an antibody in *E. coli* cells. Although CHO cells are mentioned, CHO cells are not singled out as being of particular importance. No actual expression is reported in CHO cells. Therefore, these references are less relevant than the Shively references.

The following references pertain to anti-CEA antibodies:

Cabilly et al.	1989 USP 4816567	
Cabilly et al.	1984 EP 0125023 A1	
Cabilly et al.	1991 EP 0125023 B1	
Cabilly et al.	1984	PNAS USA 81(11):3273-3277
Cabilly & Riggs	1985	Gene 40(1):157-161
Shively	1981	Meth. Enzymol. 79:31-48
Shively et al.	1992 USP 5081235	
Shively	2000	Declaration of John E. Shively
Shively	2001	Deposition Transcript of Shively
Neumaier et al.,	1990, Cancer Res. 50:2128-2134.	
Duda et al.,	1990, Surgical Onc. 44:73-77	

Campath Antibodies

Prior to October 16, 1991, Campath, an antibody against CDw52, was developed by Medical Research Council in Cambridge, United Kingdom. The antibody was engineered and expressed in several different cell lines prior to the humanized IgG1 variant being expressed in Chinese Hamster ovary cells. Predecessors to

Campath-1H, other variants of the Campath antibody, were shown to be therapeutic.

The following documents and references pertain to the Campath antibody:

Crowe et al., 1992, Clin. Exp. Immunol. 87:105-110.
Cobbold, 1991, Imm. Letters 29:117-122.
Cobbold & Waldmann, 1984, Nature 308(5958):460-462
Hale, 1983, Mol. Biol. Med. 1:21-334.
Hale, 1990, Progress Report - MRC Wellcome Ther. Antibody Centre
Hale et al., 1988, Lancet 2(8625):1394-1399.
Finnegan et al., 1997, J. Rheumatol. 24(7):1448-1449
Riechmann et al., 1988, J. Mol. Biol. 203(3):825-828.
Riechmann et al., 1988, Nature 332(6162):323-327.
Trial Transcript 2758:1-2762:18, 2807:7-2815:15, 2819:7-2821:7

Herceptin

It is Genentech's assertion that certain work was performed with the Herceptin antibody before the earliest U. S. filing date of the Page application (Trial Transcript 1713:5-1724:12, 2788:5-2792:6).

Rituxan

It is Genentech's assertion that in the fall of 1990, IDEC Pharmaceuticals started working on Rituxan and that Phase II clinical trials started in 1994, or late 1993 (Trial Transcript 1786:9-1787:25)

Anti-human placental alkaline phosphatase antibody

DeWaele, et al, Eur. J. Biochem. Vol. 176, 287-295(1988).
Trial Transcript 2768:12-2770:14.

Therapeutic proteins (other than recombinant antibodies) expressed by and/or glycosylated in CHO cells

Prior to the October 16, 1991 filing date, various proteins (other than recombinant antibodies as used in the claims of the present application) were expressed in CHO cells. Some of these proteins were successfully used to treat human patients prior to October 16, 1991. A summary of these proteins follows.

Genentech asserts that in 1983, Genentech was using *E. coli*, yeast and cell lines (including CHO) to express various proteins (Trial Transcript, 1687:5-15).

Genentech also asserts that in 1983, Genentech was working with DHFR⁻ CHO cell strain to express proteins. It is asserted that this strain was known to produce high levels of proteins (Trial Transcript 1687:25-1688:25).

Tissue Plasminogen Activator (t-PA)

(Trial Transcript 1695: 13-22, 1780:22-1783:4, 2753:2-2757:25)

Recombinant t-PA was expressed in CHO cells, approved by the FDA and used to treat patients in the 1980s. The t-PA was expressed in a CHO K1 derived cell line that was defective in DHFR.

Hepatitis B Vaccine

(Trial Transcript 1698:14-1699:13)

This vaccine, which involved glycoproteins, was in development in 1983-1984 and was expressed in CHO cells.

Factor VIII

(Trial Transcript 1699:14-1701:16)

Factor VIII is a large glycoprotein. It was expressed in CHO cells in the 1983-1984 time frame (Trial Transcript 1700:16-19)

CD4 IgG/Fragments/Hybrid Immunoglobulins

(Trial Transcript 1701:17-1705:10, 1767:4-1779:17, 2785:2-2788:4)

This group of references includes immunoadhesins, and fragments of antibodies. Some of these molecule were expressed in CHO cells in the late 1980s.

Various references were introduced in the interference (Exhibits 1016-1021, which correspond to USPatents 5,116,964, 5,225,538, 5,336,603, 5,428,130, 5,455,165 and 5,514,582, respectively) describe molecules identified as "hybrid immunoglobulins", "heterofunctional immunoadhesons", etc. These molecules are not antibodies. They are fusion proteins that lack antibody binding domains.

Capon et al.	1992	USP 5116964
Capon et al.	1993	USP 5225538
Capon et al.	1994	USP 5336603

Capon et al.	1995	USP 5428130
Capon et al.	1995	USP 5455165
Capon et al.	1996	USP 5514582
Harris et al	1990	J. Biochem. Vol. 194, 611-620
Sekigawa et al.	1990	J. Virology 64:5194-5198
Routledge et al.	1991	Eur. J. Immunol. 21:2717-2725
USP 5605689	1997	Ammann

GP120

(Trial Transcript 1705:11-1707:7, 1779:14-1780:20)

Recombinant GP120 (HIV envelope glycoprotein 120) was expressed in CHO cells. The carbohydrate structure of the expressed protein was studied (Mizuochi et al., *Biochem. J.*, 254:599-603 (1988)).

DNase

(Trial Transcript 1707:8-1708:13)

DNase is a Genentech product that was developed in the late eighties. It is a recombinant glycoprotein product that was expressed in CHO cells and was used to treat patients with cystic fibrosis.

Other Proteins and Fragments

(Trial Transcript 1708:17-1713:21)

Other proteins or fragments that were expressed in CHO cells are cited in the references listed below.

Dyer et al., 1990, *Leukemia & Lymphoma* 2:179-193
Stevenson et al., 1991, *Blood* 77:1071-1079
Peakman et al., 1994, *Hum. Antibod. Hybrid.* 5:65-74
Routledge et al., 1991, *Eur. J. Immunol.* 21:2717-2725,

Information Relevant to Inventorship

During the Interference and the District Court litigation, Genentech questioned whether the designation of inventorship of the Page patents, the parent to this divisional application, was

proper. The positions of the parties on this issue are set forth in Cabilly Preliminary Motion 5, the Opposition by Glaxo and the Reply by Cabilly. After considering all information relevant to this issue, applicants have determined that the inventorship of the already issued Page patents (USPS 5,545,403, 5,545,404 and 5,545,405) is proper. It is also believed that Drs. Page and Crowe are coinventors of the claims of the present application.

Information Relevant to Enablement

Genentech has questioned the enablement of the claims of the Page patents. The positions of the parties are set forth in Cabilly Preliminary Motion 4, the Opposition by Glaxo and the Reply by Cabilly. It is Glaxo's position that the claims of the Page patents and the claims of the present application fully comply with 35 USC 112. The claims recite the essential features of the invention. The claimed invention has applicability to various types of recombinant antibodies expressed in CHO cells.

III. FEES

This Information Disclosure Statement is being filed concurrent with the filing of a divisional patent application; therefore, no fee is required.

If the Examiner has any questions concerning this IDS or requires a copy of any of the references cited but not provided, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fee required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Enclosures: ☒ PTO-1449
☒ Reference (1 reference only)
☐ Foreign Search Report
☐ Other:

(Rev. 11/02/01)

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)	ATTY DOCKET NO. 2801-0208P	APPLICATION NO. NEW-Rule 53(b) Div. of 10/145,712
	APPLICANT Martin J. PAGE et al.	
	FILING DATE January 28, 2004	GROUP Unassigned

U.S. PATENT DOCUMENTS

Examiner Initials	ID	Document Number	Year	Name	Class	SubClass	Filing Date
		USP 5605689	1997	Ammann			
		USP 4399216	1983	Axel et al.			
		USP 4456748	1984	Goeddel			
		USP 4816567	1989	Cabilly et al.			
		USP 5081235	1992	Shively et al.			
		USP 5098833	1992	Lasky et al.			
		USP 5116964	1992	Capon et al.			
		USP 5225538	1993	Capon et al.			
		USP 5336603	1994	Capon et al.			
		USP 5428130	1995	Capon et al.			
		USP 5455165	1995	Capon et al.			
		USP 5514582	1996	Capon et al.			
		USP 5460811	1995	Goeddel et al.			
		USP 5500362	1996	Robinson et al.			
		USP 5545403	1996	Page et al.			
		USP 5545404	1996	Page			
		USP 5545405	1996	Page			
		USP 5721108	1998	Robinson et al.			
		USP 5876961	1999	Crowe et al.			
		USP 5877293	1999	Adair et al.			
		USP 5985279	1999	Waldmann et al.			
		USP 6120767	2000	Robinson et al.			
		USP 5089397	1992	Kushner et al.			
		USP 5219996	1993	Bodmer et al.			
		USP 6020153	2000	Hardman et al.			
		USP 6010902	2000	Ledbetter et al.			
		USP 5,846,534	1998	Waldmann et al.			
		USP 6,331,415	2001	Cabilly et al.			
		USP 5,417,970	1995	Roskam et al.			

Examiner**Date Considered**

Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

[illegible]

Examiner

Date Considered

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OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

	Ashford et al., 1993, J. Biol. Chem. 268(5):3260-3267
	Baker et al., 1991, Antibodies, Immunoconjugates and Radiopharmaceuticals, 4:799-809.
	Beatty et al., 1989, Cancer Res. 49:1587-1594.
	Beatty et al., 1990, Cancer Res. 50:922s-926s.
	Benjamin et al., 1986, Nature 320:449-451.
	Bindon et al., 1985, Transplant. 40(5):538-544
	Bruggemann et al., 1987, J. Exp. Med. 166(5):1351-1361
	Byrn et al., 1990, Nature 344:667-670.
	Cabilly et al., 1984, PNAS USA 81(11):3273-3277
	Cabilly & Riggs, 1985, Gene 40(1):157-161.
	Cobbold, et al., pp.139-154, in Bone Marrow Purging and Processing and Processing, c.1990 by Alan R. Liss, Inc.
	Cobbold, 1991, Imm. Letters 29:117-122.
	Cobbold & Waldmann, 1984, Nature 308(5958):460-462.
	Cohen et al., 1972, PNAS USA 69(8):2110-2114.
	Colcher et al., 1989, Cancer Res. 49:1738-1745.
	Cosimi et al., 1990, Surgery 108(2):406-414.
	Crowe et al., 1992, Clin. Exp. Immunol. 87:105-110.
	Curti, 1993, Crit. Rev. in Oncol./Hematol. 14:29-39.
	Dall'Acqua & Carter, 1998, Curr. Op. In Biotech. 8:443-450.
	Davis et al., 1990, J. Biol. Chem. 265:10410-10418.
	Dillman, 1989, Ann. Int. Med. 111:592-600.
	DiMaggio J. et al., pp.177-203 in Cancer Chemo. & Biol. Resp. Mod. Vol. 11, J. Pinedo et al. (eds.) c. 1990 by Elsevier.
	De Waele et al., 1988, Eur. J. Biochem. 176:287-295.
	Duda et al., 1990, J. Surgical Onc. 44:73-77.
	Dyer et al., 1990, Blood 75:709-714.
	Dyer et al., 1990, Leukemia & Lymphoma 2:179-193.
	Ebert, 1991, Dissertation, University for Soil Cultivation in Vienna, Austria: 1-96.

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		Feys et al., 1988, Int. J. Cancer Suppl. 2:26-27.	
		Field et al., 1990, 10th Mtg Euro. Soc. For Ani. Cell Tech., Spier et al., Eds. Pp. 742-744.	
		Fukuda et al., 1989, Blood 73(1):84-89.	
		Geisse et al., 1996, Protein Exp & Pur. 8:271-282.	
		Gillies et al., 1989, Bio/Tech. 7:799-804.	
		Goeddel et al., 1979, Nature 281(5732):544-548.	
		Goeddel et al., 1980, Nuc. Acids Res. 8(18):4057-4074.	
		Goochee & Monica, 1990, Bio/Tech. 8:421-427.	
		Goochee et al., 1991, Bio/Tech. 9:1347-1355.	
		Gorman et al., 1991, PNAS 88:4181-4185.	
		Hale, 1983, Mol. Biol. Med. 1:321-334.	
		Hale, 1990, Excerpt from Progress Report - MRC Wellcome Ther. Antibody Centre.	
		Hale et al., 1985, Br. J. of Haematol. 60(1):41-48.	
		Hale et al., 1988, Lancet 2(8625):1394-1399.	
		Hale et al., 1990, Tissue Antigens 35:118-127.	
		Harabayashi et al., 1991, Mitsubishi Kasei R&D Rev. 5(1):85-91.	
		Harris et al., 1990, Proc. 34 th Oholo Conf, Eilat, Israel pgs. 465-477.	
		Harris et al., 1993, TIBTECH 11:42-44.	
		Haynes, 1983, Nucl. Acids Res. 11:687-706.	
		Hird et al., pp.183-189 in Genes & Cancer, Carner & Sikora (eds.), c.1990 by J. Wiley & Sons.	
		Hutzell et al., 1991, Cancer Res. 51:181-189.	
		Joziassse et al., 1999, Subcell Biochem. 32:25-48.	
		Joziassse et al., Eur. J. Biochem., 267:6501-6508 (2000).	
		Kaetzel et al., 1985, PNAS USA 82:7280-7283.	
		Kaetzel et al., 1988, J. Biol. Chem. 263(13):6344-6351.	
		Kagawa et al., 1988, J. Biol. Chem. 263(33):17508-17515.	
		Kaufman et al., 1985, Mol. Cell. Biol. 5(7):1750-1759.	
		Kaufman et al., 1990, Meth. Enzymol. 185:537-566.	
		Kaufman et al., 1986, PNAS USA 83:3136-3140.	
		Khazaeli, Meredith et al., 1990, Abstract Submission, "Pharmacokinetics of Single and Repeated Therapeutic...", 3 rd Ann. Conf. On Radioimmunodetection and Radioimmunotherapy of Cancer.	

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		APPLICANT Martin J. PAGE et al.	
		FILING DATE January 28, 2004	GROUP Unassigned

	Khazaeli, Plott et al., 1990, Abstract Submission, "Pharmacokinetics of Treatment Doses of Chimera I-131 B72.3 in Colorectal Carcinoma Patients"; 37 th Ann. Mtg. Soc. Of Nuclear Med.
	Khazaeli et al., 1991, Cancer Res. 51:5461-5466.
	Khazaeli et al., "Frequent Anti-V Region Immune Response to Mouse B72.3 Monoclonal Antibody", J. Clin. Immunol. (submitted)
	Klein et al., 1981, PNAS USA 78(1):524-528.
	Kuzel et al., 1990, Oncol. 4(3):77-84, 89.
	Kyle et al., 1989, Ann. Rheum Dis 48(5):428-429, (Abstract).
	Leatherbarrow et al., 1985, Mol. Immunol. 22(4):407-415.
	Lifely et al., 1995, Glycobiol. 5(3):813-822.
	Lim et al., 1993, Lancet 341:432-433.
	LoBuglio et al., Abstract Submission, 3 rd Conf. On Radiodetection and Radioimmunotherapy of Cancer, "Human Immune Response to Chemeric B72.3(γ4)".
	LoBuglio & Saleh, 1992, Am. J. Med. Sci. 304(3):214-224.
	LoBuglio et al., 1989, PNAS USA 86:4220-4224.
	LoBuglio et al., pp.291-295 in Advances in the Applications of Monoclonal Antibodies in Clinical Oncology, Chapman & Hall (eds.), c. 1991.
	LoBuglio et al., 1992, Abstract Submission, ASCO Annual Meeting, "Dose Fractionation Trial of ¹³¹ I-Chimera B72.3 In Patients With Metastatic Colon Cancer".
	LoBuglio et al., 2000, Deposition in Interference 104,532.
	Lockwood et al., 1993, Lancet 341:1620-1622.
	Lyons et al., 1990, Protein Eng. 3(8):703-708,
	Martz, 1998, BancBoston Analyst Report, Healthcare Res. Pgs. 69-86.
	Mathieson et al., 1990, New England J. of Med. 323(4):250-254,
	Meredith et al., 1990, Abstract Submission 5 th Congress of World Federation of Nuclear Biology and Medicine, "Diagnostic and Therapeutic Doses of Radiolabeled Mouse/Human Chimeric Monoclonal Antibodies".
	Meredith et al., 1990, Abstract Submission, 3 rd Annual Conference on Radioimmunodetection and Radioimmunotherapy of Cancer, "Phase I Trial of ¹³¹ I-Chimeric Mouse/Human B72.3 (Anti-Tag-72) in Patients with Metastatic Colon Cancer".
	Meredith et al., 1990, Abstract Submission, Soc. Nucl. Med. 37 th Ann. Meeting, "Body Distribution of Two I-131-Labeled Chimeric Monoclonal Antibodies".
	Meredith et al., 1991, J. Nuc. Med. 32(6):1162-1168.
	Meredith et al., 1992, J. Nuc. Med. 33(1):23-29.
	Meredith, 1990, Protocol: UAC 180 NCI:T89-0144 (NCI/CTEP Sheets)

Examiner**Date Considered**

Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered.
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INFORMATION DISCLOSURE CITATION IN AN APPLICATION (Use several sheets if necessary)		APPLICANT Martin J. PAGE et al.	
		FILING DATE January 28, 2004	GROUP Unassigned

	Meredith et al., 1989, Protocol: UAC 180.
	Meredith et al., 1990, Protocol: UAC 180 (Amended)
	Meredith et al., 1995, J. Nuc. Med. 36:2229-2233.
	Meredith et al., Med. Physics "Dosimetry of Solid Tumors" (submitted)
	Mizouchi et al., 1988, Biochem. J. 254:599-603.
	Morrison et al., 1984, PNAS USA 81(21): 6851-6855.
	Morrison et al., 1988, Cancer Invest. 6(2):185-192.
	Morrison et al., 1988, Clin. Chem. 34(9):1668-1675.
	Nadler et al., 1980, Cancer Res. 40:3147-3154.
	Nadler et al., 1980, J. Immunol. 125(2):570-577.
	Nakatani et al., 1989, Bio/Tech. 7:805-810.
	Neuberger et al., 1984, Nature 312(5995):604-608.
	Neuhaus et al., 1989, JACC 14:1566-1569.
	Neumaier et al., 1990, Cancer Res. 50:2128-2134.
	Nishimura Y et al., Recombinant Human-Mouse Chimeric Monoclonal Antibody Specific for common Actue Lymphocytic Leykemia Antigen", Database accession No. PREV198784006235 XP 002238118 (Abstract Only)
	Nose & Wigzell, 1983, PNAS USA 80:6632-6635.
	Oh-eda et al., 1990, J. Biol. Chem. 265(20):11432-11435.
	Osband et al., 1990, Immunol. Today 11(6):193-195.
	Page & Sydenham, 1991, Bio/Tech. 9:64-68.
	Paul, MD (Ed), 1993, "IgG Subclasses" Fundamental Immunol. 3rd Ed. Chap 22, pgs. 838-839.
	Peakman et al., 1994, Hum. Antibod. Hybrid. 5:65-74.
	Poynton et al., 1993, Lancet 341:1037.
	Primus et al., 1990, Cancer Immunol. & Immunother. 31:349-357.
	Rademacher et al., 1988, Ann. Rev. Biochem. 57:785-838.
	Raju et al., 1996, Biotechnol. Appl. Biochem. 24:191-194.
	Raju et al., 2000, Glycobiol. 10(5):477-486.
	Rhodes, 1988, Adv. Anim. Cell. Biol. Technol. Bioprocess 472-474.
	Rhodes & Birch, 1988, Bio/Tech. 6:518-523.
	Riechmann et al., 1988, J. Mol. Biol. 203(3):825-828.
	Riechmann et al., 1988, Nature 332(6162):323-327.
	Ringold et al., Journal of Molecular and Applied Genetics, Vol. 1, No. 3, pp.165-175 (1981)

Examiner**Date Considered**

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	APPLICANT Martin J. PAGE et al.	
	FILING DATE January 28, 2004	GROUP Unassigned

		Routledge et al., 1991, Eur. J. Immunol. 21:2717-2725.
		Ruker et al., 1991, Ann. NY Acad. Of Sci. Recom. DNA Tech. I 646:212-219.
		Schlom et al., 1980, PNAS USA 77(11):6841-6845.
		Seaver, 1994, Genetic Eng. News 14(14):10, 21.
		Sekigawa et al., 1990, J. Virology 64:5194-5198.
		Shively, Declaration of October 30, 2000
		Shively, Deposition Transcript Interference 104,532
		Smith et al., 1990, J. Biol. Chem. 265(11):6225-6234.
		Spellman et al., 1989, J. Biol. Chem. 264:14100-14111.
		Stevenson et al., 1989, Anti-Cancer Drug Des. 3:219-230.
		Stevenson et al., 1991, Blood 77:1071-1079.
		Takeuchi et al., 1988, J. Biol. Chem. 263:3657-3663.
		Urlab & Chasin, 1980, PNAS USA 77:4216-4220.
		van Nagell et al., 1980, Cancer Res. 40(3):502-506.
		Vandamme et al., 1990, Eur. J. Biochem. 192:767-775.
		Waldmann, 1991, Science 252:1657-1662.
		Waldmann, 2000, Ann. Oncol. 11(Suppl. 1(3)):101-106.
		Waldmann & Goldman, 1989, Am. J. Kidney Dis. 14(5)(Suppl. 2):45-53.
		Waldmann et al., 1984, Lancet 2(8401):483-486.
		Ward et al., 1991, Nature 352:434-436.
		Weidle et al., 1987, Gene 51(1):21-29.
		Weidle et al., 1987, Gene 60(2-3):205-216.
		Weikert et al., 1999, Nature Biotech. 17:1116-1121.
		Whittle et al., 1987, Protein Eng. 1(6):499-505.
		Wilhelm et al., 1990, Bio/Tech. 8:321-325.
		Williams et al., 1990, Cancer Res. 50 (suppl.):1029s-1030s.
		Wood et al., 1990, J. Immunol. 145(9):3011-3016.
		Yarrenton, 2000, Deposition in Interference 104,532.
		Zettlmeisl et al., 1987, Bio/Tech. 5:720-725.
		Activase (Altepare) package insert
		1990, Status Report: Phase I Contract (NO1-CM-97611) CTEP.
		1991, Status Report Phase I Contract (NO1-CM-97611) CTEP.

Form PTO-1449	ATTY DOCKET NO.	APPLICATION NO.
---------------	-----------------	-----------------

Examiner**Date Considered**

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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLAS S	SUB CLASS	TRANSLATION	
						YES	NO
OTHER DOCUMENTS (Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.							
	1992, Status Report Phase I Contract (NO1-CM-97611) CTEP.						
	Jury Verdict from Civil Action No. 99-335 (RRM), Glaxo Wellcome, Inc. v. Genentech, Inc. (2001)						
	Ashwell & Harford, 1982, <i>Ann. Rev. Biochem.</i> 51:531-554.						
	Boyd et al., 1995, <i>Mol. Immunol.</i> 32(17/18):1311-1318.						
	Carr et al., 1989, <i>J. of Biol. Chem.</i> 264(35):21286-21295.						
	Conradt et al., 1987, <i>J. of Biol. Chem.</i> 262(30):14600-14605.						
	Fujii et al., 1990, <i>J. of Biol. Chem.</i> 265(11):6009-6018.						
	Jefferis & Lund, 1997, <i>Chem. Immunol.</i> 65:111-128.						
	Kornfeld et al., 1971, <i>J. of Biol. Chem.</i> (10):3259-3268.						
	Mattu et al., 1998, <i>J. of Biol. Chem.</i> 273(4):2260-2272.						
	Parekh et al., 1985, <i>Nature</i> 316:452-457.						
	Parekh et al., 1989, <i>Biochem.</i> 28:7644-7662.						
	Parekh et al., 1989, <i>Biochem.</i> 28:7670-7679.						
	Rademacher et al., 1983, <i>Biol. Soc. Transactions</i> (11)2:132-134.						
	Rothman et al., 1989, <i>Mol. Immunol.</i> 26(12):1113-1123.						
	Sasaki et al., 1987, <i>J. of Biol. Chem.</i> 262(25):12059-12076.						
	Sutton & Phillips, 1983, <i>Biol. Soc. Transactions</i> (11)2:130-132.						
	Written Questioning in JP 333868/91 with Translation and Comments						

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